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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/994,495	SOMACK ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *20-47 and 51-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 48-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07 May 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-19 and 48-50 in Paper No. 7 is acknowledged.

2. Claims 20-47 and 51-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Information Disclosure Statement

3. The information disclosure statement filed 07 May 2004 has been considered and made of record.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Instant claim 50, is drawn to the combination of a plate device with through holes and a sealing device that includes recesses to individually seal each of the end openings of the plate. Claims 48-50 appear to be drawn to a second embodiment of the invention shown in Figures 7-11. The disclosure of this embodiment does not provide antecedent basis for the combination of a sealing tray (24) of the first embodiment with the plate (58) of the second embodiment. Are

applicants attempting to claim waste plate (82) as the sealing device with recesses? Clarification and/or correction is requested.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-5, 16 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Franciskovich et al.(US 5,603,899).

With respect to claims 1 and 16, the reference of Franciskovich et al. discloses a system for processing a plurality of fluid samples that includes a plurality of biological sample purification devices (12). Each device (12) comprising a tubular body (50) having a first end (62), a first end opening (70), a second end (54), a second end opening (52) and a species-immobilizing filter (51,53) held within the tubular body (50). The system includes removable caps (58) for sealing the second end opening (52) and a sealing device (16) having a surface (36) adapted to individually seal each of the first end openings (70).

With respect to claims 2 and 19, the surface (36) of the sealing device (16) has a plurality of recesses (34) therein.

With respect to claims 3-5, the reference also discloses the use of caps (64,68) adapted to seal the first end openings (70).

7. Claim 48 is rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al.(US 2002/0055111).

The reference of Chen et al. discloses a system for manipulating biological samples that includes a plate or substrate (100 or 200) that includes a first surface (202) and a second surface (204) that opposes the first surface and through holes extending between the surfaces. Each through hole includes a species-immobilizing filter (3D internal probe microarray). The reference also discloses sealing the openings using adhesive films (See paragraph [0057]).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 3-9, 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franciskovich et al.(US 5,603,899) in view of Nix et al.(US 6,402,950).

The reference of Franciskovich et al. discloses a system for processing a plurality of fluid samples that includes a plurality of biological sample purification devices (12). Each device (12) comprising a tubular body (50) having a first end (54), a first end opening (52), a second end (62), a second end opening (70) and a species-immobilizing filter (51,53) held within the tubular body (50). The system includes removable caps (64,68) for sealing the second end opening (70).

With respect to claim 1, while the reference discloses the use of caps (58) for individually sealing each of the first end opening (52), the reference fails to disclose the use of a sealing device having a surface adapted to individually seal each of the first end openings.

The reference of Nix et al. discloses that it is known in the art to seal the first end openings (108) of a plurality of separation devices similar to those of the reference of Franciskovich et al. using a sealing device (adhesive film or foil) having a surface adapted to individually seal each of the first end openings (108) (See column 8, line 63, to column 9, line 4).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a sealing film as suggested by the reference of Nix et al. in place of the caps of the primary reference for the known and expected result of providing an alternative means recognized in the art to achieve the same result, sealing the open ends of a plurality of separation devices.

With respect to claims 3-5, the reference of Franciskovich et al. discloses that the first end openings can be sealed with caps (58) and the second end openings sealed with caps (64,68).

With respect to claims 6 and 7, the filter is located at the second end (62) of the device.

With respect to claims 8 and 9, when using the sealing device as suggested by the reference of Nix et al., the sealing device would include an adhesive. The specifics of the adhesive would have been well within the purview of one having ordinary skill in the art based merely on considerations such as whether or not the seal is intended to be permanent or temporary.

With respect to claim 16, when using the sealing device as suggested by the reference of Nix et al., the structure would be in the form of an assembly.

With respect to claim 17, the reference of Franciskovich et al. discloses the use of a sealing device (16) having a surface (36) adapted to seal the second end openings (70).

With respect to claim 18, the sealing device (16) of the reference of Franciskovich et al. includes recesses (34) for receiving the second end openings (70).

12. Claims 1-9 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franciskovich et al.(US 5,603,899) in view of in view of Sanadi (US 5,741,463).

The reference of Franciskovich et al. discloses a system for processing a plurality of fluid samples that includes a plurality of biological sample purification devices (12). Each device (12) comprising a tubular body (50) having a first end (54), a first end opening (52), a second end (62), a second end opening (70) and a species-immobilizing filter (51,53) held within the tubular body (50). The system includes removable caps (64,68) for sealing the second end opening (70).

With respect to claim 1, while the reference discloses the use of caps (58) for individually sealing each of the first end opening (52), the reference fails to disclose the use of a sealing device having a surface adapted to individually seal each of the first end openings.

The reference of Sanadi discloses a variety of well-known means for sealing the openings of an array of openings of an array of tube (See column 1, lines 34-64). Figure 1 discloses the use of a sealing device (1,2) that has a surface for individually sealing each of the openings.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a sealing device as suggested by the reference of Sanadi for the known and expected result of providing a means known in the art for sealing an array of openings. Use of the device of Sanadi would be advantageous because it would eliminate the need for an individual cap for each opening while providing the sealing suggested by the primary reference of Franciskovich et al.(See column 1, lines 34-64, of Sanadi).

Claims 2 and 19 differ by reciting that the sealing device for the first end openings (52) include recesses for receiving the ends of the tubular bodies (50).

Figure 4A of Sanadi discloses an alternative-sealing device that includes a plurality of recesses formed by elements (73).

In view of this teaching, it would have been obvious to provide recesses as suggested by Sanadi for the known and expected result of providing an alternative means recognized in the art to achieve the same result, sealing an array of openings.

With respect to claims 3-5, the reference of Franciskovich et al. discloses that the first end openings can be sealed with caps (58) and the second end openings sealed with caps (64,68).

With respect to claims 6 and 7, the filter is located at the second end (62) of the device.

With respect to claims 8 and 9, the reference of Sanadi discloses that the use of a sealing tape is a well known alternative to the use of caps or the use of the device of Figures 1 or 4A of the reference of Sanadi (See column 1, lines 34-64).

With respect to claim 16, when using the sealing device as suggested by the reference of Sanadi, the structure would be in the form of an assembly.

With respect to claim 17, the reference of Franciskovich et al. discloses the use of a sealing device (16) having a surface (36) adapted to seal the second end openings (70).

With respect to claim 18, the sealing device (16) of the reference of Franciskovich et al. includes recesses (34) for receiving the second end openings (70).

13. Claims 10, 11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franciskovich et al.(US 5,603,899) in view of Bankier et al.(US 5,846,493).

The reference of Franciskovich et al. has been discussed above.

With respect to claims 10 and 11, while the reference of Franciskovich et al. employs a species-immobilizing filter (51,53), the reference does not disclose that the filter is disclosed as a nucleic acid purification filter that can bind nucleic acids.

The reference of Bankier et al. discloses that it is known in the art to provide an array of separation columns (1) that are similar to that of the primary reference of Franciskovich et al. with a nucleic acid purification filter (38) that can bind nucleic acids.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a separation filter as disclosed by the reference of Bankier et al. in the device of the primary reference for the known and expected result of separating nucleic acids from biological samples while providing the advantages of the column system disclosed by the primary reference of Franciskovich et al.

With respect to claims 13-15, while the device of the modified reference as discussed above is employed for the purification of DNA fragments from a sample, the reference is silent as to the source of the sample. However, cell lysates, whole blood and tissue extracts are all known in the art to be sources of nucleic acid samples. As a result, it would have been obvious to one of ordinary skill in the art to employ any well-known source of nucleic acid based merely on the intended sample to be analyzed.

14. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Franciskovich et al.(US 5,603,899) in view of Bankier et al.(US 5,846,493) taken further in view of Leying et al.(US 5,955,271) and Sheer et al.(US 5,124,041).

The combination of the references of Franciskovich et al. and Bankier et al. has been discussed above.

The above claim differs by reciting that the system includes a polymerase solution in the purification device.

The reference of Leying et al. discloses that it is well known in the art to purify and amplify nucleic acid in the same vessel (See Example 1).

The reference of Sheer et al. discloses that it is known in the art to perform PCR in situ on the purification media of a device (See column 8, lines 46-47).

In view of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system with PCR reagents for the known and expected result of performing PCR on the purified sample in the filter device. As shown in the prior art, in situ PCR is an acceptable alternative to elution of the purified nucleic acid that is amplified in a separate vessel.

15. Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fernwood et al.(US 5,151,719) in view of Sanadi (US 5,741,463).

The reference of Fernwood et al. discloses a plate (11,16) having a first surface and a second surface that opposes the first surface and a plurality of through-holes (12, 41) where each through-hole extend from the first surface to the second surface and define a first opening at the first surface and a second opening at the second surface (See Figure 4). The plate includes a plurality of species-immobilizing filters (13) disposed in each through-hole. The reference discloses that the filter can be a continuous sheet or individual disks (See column 3, lines 12-30). Note a membrane sheet or disk (13) clamped between members (11 and 16) result in a plate device (11,16) with a filter (13) immobilized within the through holes (12,41) of the device.

Claim 48 differs by reciting that the system includes a first sealing device adapted to individually seal each of the first openings and a second sealing device adapted to seal each

second end opening. Dependent claim 49 specifies that the first sealing device is a plurality of caps.

The reference of Sanadi discloses that when using an array of tube or multi-well plates (with or without a filtration feature) contamination of the samples within the individual wells or tubes is a problem (See column 1, lines 34-44). The reference also discloses a number of devices known in the art for sealing the openings associated with arrays of tubes or wells. The devices include plates, tapes and caps (See column 1, lines 44-64). Figure 1 discloses the use of a sealing device (1,2) that has a surface for individually sealing each of the openings.

In view of this teaching, it would have been well within the purview of one having ordinary skill in the art to employ any of the sealing devices discussed by the reference of Sandi to seal the openings of an array device, such as that of the primary reference of Fernwood et al., with a sealing film or individual caps for the known and expected result of preventing contamination of the wells of the array device.

With respect to claim 50, Figure 4A of Sanadi discloses an alternative-sealing device that includes a plurality of recesses formed by elements (73). In view of this teaching, it would have been obvious to provide recesses as suggested by Sanadi for the known and expected result of providing an alternative means recognized in the art to achieve the same result, sealing an array of openings.

16. Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGraw et al. in view of Sanadi (US 5,741,463).

The reference of McGraw et al. discloses a plate (8) having a first surface and a second surface that opposes the first surface and a plurality of through-holes (11) where each through-hole extend from the first surface to the second surface and define a first opening at the first surface and a second opening at the second surface (See Figure 1B and Figure 1C). The plate includes a plurality of species-immobilizing filters (7) disposed in each through-hole.

Claim 48 differs by reciting that the system includes a first sealing device adapted to individually seal each of the first openings and a second sealing device adapted to seal each second end opening. Dependent claim 49 specifies that the first sealing device is a plurality of caps.

The reference of Sanadi discloses that when using an array of tube or multi-well plates (with or without a filtration feature) contamination of the samples within the individual wells or tubes is a problem (See column 1, lines 34-44). The reference also discloses a number of devices known in the art for sealing the openings associated with arrays of tubes or wells. The devices include plates, tapes and caps (See column 1, lines 44-64). Figure 1 discloses the use of a sealing device (1,2) that has a surface for individually sealing each of the openings.

In view of this teaching, it would have been well within the purview of one having ordinary skill in the art to employ any of the sealing devices discussed by the reference of Sandi to seal the openings of an array device, such as that of the primary reference of McGraw et al., with a sealing film or individual caps for the known and expected result of preventing contamination of the wells of the array device.

With respect to claim 50, Figure 4A of Sanadi discloses an alternative-sealing device that includes a plurality of recesses formed by elements (73). In view of this teaching, it would have

been obvious to provide recesses as suggested by Sanadi for the known and expected result of providing an alternative means recognized in the art to achieve the same result, sealing an array of openings.

Response to Arguments

17. Applicant's arguments, see pages 13-20, filed 19 May 2004, with respect to the rejection of the claims over various combinations of references that include the reference of Krueger (US 3,295,686) have been fully considered and are persuasive. The rejection of the claims has been withdrawn and new grounds of rejection have been made using the newly cited references of Franciskovich et al.(US 5,603,899); Chen et al.(US 2002/0055111) and McGraw et al. (US 5,368,823).

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H. Beisner
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WHB